UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Solvay Pharmaceuticals, Inc.,

Plaintiff,

v.

Global Pharmaceuticals; and
Impax Laboratories, Inc.,

Defendants;

and

Ethex,

Movant;

and

Global Pharmaceuticals; and
Impax Laboratories, Inc.,

Counter-Claimants,

v.

Solvay Pharmaceuticals, Inc.,

Counter-Defendant.

Civil No. 03-2854 (DWF/SRN)

MEMORANDUM OPINION AND ORDER

Saul H. Perloff, Esq., Lisa Horvath Shub, Esq., and Marc B. Collier, Esq., Fulbright & Jaworski; and Peter J. Goss, Esq., and John B. Gordon, Esq., Faegre & Benson LLP, counsel for Plaintiff and Counter-Defendant.

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Venable LLP; and John B. Lunseth, II, Esq., Jay W. Schlosser, Esq., and Michael M. Lafeber, Esq., Briggs & Morgan, PA, counsel for Defendants and Counter-Claimants.

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Introduction

The above-entitled matter came before the undersigned United States District Judge on January 6, 2006, pursuant to a Motion for Partial Summary Judgment brought by Plaintiff Solvay Pharmaceuticals, Inc. ("Solvay"), and pursuant to a Motion for Summary Judgment brought by Defendants Global Pharmaceuticals and Impax Laboratories, Inc. (collectively, "Global"). For the reasons set forth below, Solvay's motion is granted in part and denied in part; Global's motion is granted in part and denied in part.

Background

This case involves a dispute over Global's marketing of a purported generic alternative to Solvay's pancrelipase, or pancreatic enzyme, supplements. Pancreatic enzyme supplements are used to treat cystic fibrosis patients and others who suffer from pancreatic exocrine insufficiency, a disorder that keeps their bodies from producing the proper enzymes to digest food. The active ingredient in these products is pancrelipase, an extract derived from pig pancreases that contains primary lipase, protease, and amylase, the three principal enzymes that a healthy pancreas secretes and that are critical to digestion. Undisputedly, the coating process on the pancreatic enzyme supplements is important because the effectiveness of the supplements depends upon the amount of the active enzyme that reaches the patient's duodenum, or upper small intestine, where a

healthy pancreas would normally deliver the enzymes. The "enteric" coating on the supplements ensures that stomach acid does not entirely reduce the enzyme activity of the supplement before the enzymes reach the duodenum. Solvay contends that each manufacturer's approach to the formulation, blending, and coating of these supplements can lead to differences in enzyme activity and release rates, even if the supplements are labeled as containing the same enzyme content.

Solvay develops, manufactures, and markets the Creon line of prescription microencapsulated pancreatic enzyme supplements. Solvay has been selling Creon in the United States since 1987 under the name of Creon Microspheres. In 1993, Solvay introduced a refined product called Creon Minimicrospheres, which reduced the size of the pancrelipase spheres. Solvay's current line of pancreatic enzyme supplements includes Creon 5, Creon 10, and Creon 20, based upon how many units of the lipase enzyme each product contains. Global Pharmaceuticals is the generic marketing division of Impax Laboratories, Inc. In 1998, Global began to market a pancreatic enzyme supplement under the trade name Lipram. In 1999, Global began to market Lipram-CR, a product positioned as an alternative to Creon. Ultimately, Global marketed Lipram CR5, CR10, and CR20 based upon how many units of the lipase enzyme each of their products contains.

Pancreatic enzyme supplements were available over-the-counter until 1995. In July 1991, the FDA issued a proposed rule that all pancreatic enzyme supplements were "new drugs" that would require the submission and approval of a New Drug Application ("NDA"). In 1995, the FDA issued a final rule banning over-the-counter sales of

unapproved pancrelipase products. Prescription products were still not required to receive FDA approval. In 2004, the FDA set April 28, 2008, as the deadline for manufacturers of pancreatic enzyme supplements to obtain FDA approval of their NDAs. Existing products were allowed to remain on the market until the April 2008 deadline. Solvay completed clinical studies and submitted its NDA in 1997. Solvay's NDA has not yet been approved by the FDA. Global never applied for approval of an NDA for Lipram, has never conducted human clinical trials, and does not intend to seek such approval from the FDA.

The FDA has not set standards for pancrelipase products. Instead, it is undisputed that the United States Pharmacopeia ("USP") standards govern the strength, quality, and purity of these supplements. According to the USP monograph, pancrelipase delayed-release capsules must contain lipase levels that are no less than 90% and no greater than 165% of the labeled strength, and the amylase and protease levels must be no less than 90% of the labeled strength. (Def. Ex. 10 at ¶ 24.)

I. Global's Marketing of Lipram

Solvay brought suit against Global in April 2003, alleging that Global's promotion of Lipram constituted false advertising and unfair competition. Specifically, Solvay contends that Global falsely promoted Lipram as a substitute for Creon to wholesalers, chains, distributors, mail order houses, independent pharmacies, and managed health care organizations. Solvay further alleges that Global is marketing its Lipram line of products either expressly or by implication as "generic" versions of Creon, although Solvay asserts that Lipram is not, in fact, equivalent to or substitutable for Creon. Solvay seeks $60.7

million in lost profits through January 2005 for the sale of the Lipram-CR products, the line that has been touted as a generic alternative to Creon.

Solvay contends that, from the beginning, Global embarked on a strategy to compete directly with prescription pharmaceuticals like Creon that had little or no generic competition. As to Global's specific marketing efforts, Global worked with drug wholesalers and retail drug stores to develop and increase substitution of Lipram for Creon. Global matched the color scheme of Lipram capsules to Creon. Global also worked to have major drug information databases characterize Lipram-CR as a generic substitute for Creon. As a result, when some pharmacists were presented with a Creon prescription, a message in the computer database would alert the pharmacist to the fact that Lipram could be substituted as an alternative. Global's advertising of the Lipram product touts Lipram as being a "pharmaceutical alternative" to Creon and as having the exact same amounts and ratios of the three active enzymes in Creon 10. (DEF 067121, Ex-S42.) Global's mass mailings for Lipram 10,000 tell pharmacists that Lipram is a "pharmaceutical alternative" to, a "true alternative to," and "the generic form" of Creon. (DEF 020911, Ex-S45; DEF 021809, Ex-S48; and DEF 021313–21320, Ex.-S50.) In addition, Global's "Profit Builders" advertisement, a four-page glossy ad that appeared in pharmacy trade journals and direct mailings to pharmacists, directly described Lipram as an "alternative to" Creon. (Ex-S59.)

Global contends that although it described Lipram as a "generic," an "equivalent," a "generic equivalent," or a "generic alternative," it never advertised Lipram as an FDA-approved generic, AB-rated, bioequivalent, "therapeutically equivalent," or

"pharmaceutically equivalent" to Creon. (Brief in Support of Defendants' Motion for Summary Judgment at 21.) However, Solvay points to testimony from Global representatives that people in the business understand the terms "pharmaceutical alternative" and "generic alternative" to mean the same thing. (Mitchell Goldberg Dep. at 206:3-11 (Ex. S-32).) Solvay also contends that its surveys of retail pharmacists demonstrate that 89% of pharmacists agreed that a generic substitute must be AB-rated (or therapeutically equivalent) to the name-brand product and 93% agreed that the generic must be bioequivalent to the name-brand product. (David Stewart Report at 16:1-4 (Ex-S76).) In addition, Solvay points to testimony from Global's pharmacy expert, Professor Arthur Kibbe, who stated that the "basic tenet of generic substitution is that patients will receive products that are therapeutically equivalent." (Arthur Kibbe Dep. at 108:20-112:02 (Ex-S78).) Solvay maintains that the FDA's Orange Book definition of therapeutic equivalence, which encompasses both pharmaceutical equivalents and bioequivalents, should define the terms as used in the advertising for pancreatic supplements. (*See* FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (25th ed. 2005) (the "Orange Book") at viii (Ex-S79).)

Solvay asserts that although Lipram-CR has been marketed as an alternative and generic substitute for Creon, pancreatic enzyme supplements like Creon have no true generic alternatives. Solvay contends that no pancreatic enzyme supplement has ever been demonstrated to be therapeutically equivalent, pharmaceutically equivalent, or bioequivalent to Creon or any other brand. Solvay points to FDA statements that because

the products have different formulations, the FDA does not recommend substitution. (Ex-S86 at 4.)

Solvay contends that Lipram is not pharmaceutically equivalent to Creon because it does not contain the same active ingredients in the same strength as Creon and because it does not "deliver identical amounts of the active drug ingredient over the identical dosing period" pursuant to FDA definitions of the term. 21 C.F.R. § 320.1(c). Solvay points to testimony from Global's past President, Max Mendelsohn, in which he stated that Global never tested Lipram for its pharmaceutical equivalence, bioequivalence, or therapeutic equivalence to Creon. (Max L. Mendelsohn Dep. at 129:20-130:18 (Ex-S33).) Solvay further maintains that the actual amounts of each enzyme in Lipram are not reflective of the Lipram labeling. Solvay points to tests that it conducted which confirm that the formulation of Lipram-CR and Creon is different. In addition, based on the Orange Book definition of the term "bioequivalence," Solvay and its experts assert that Lipram is not bioequivalent to Creon. Solvay maintains that its testing of the products reveals significant variation in the enzyme amounts used in Lipram versus Creon. Moreover, Solvay maintains that Global falsely marketed Lipram as meeting all United States Pharmacopeia ("USP") requirements.

Global, on the other hand, contends that *in vitro* testing of Lipram and Creon demonstrates that the two products are equivalent and produce the same clinical outcome. Global contends that Solvay has not produced any evidence that demonstrates that any patient has been harmed by the substitution of Lipram for Creon. Global further contends

that Solvay's testing of the supplements shows similar results between Lipram and Creon, and demonstrate considerable variability among the Creon samples.

Solvay also contends that, at one point, Global changed the labeling of Lipram CR10 to exactly match the lipase, amylase, and protease content of Creon10, without changing the actual enzyme strengths of the supplement. Solvay contends that Global similarly changed the labeling of their Lipram PN10 product to mimic that of the label on Pancrease—another name brand--even though the content of the product remained exactly the same. Further, Solvay maintains that even though the Lipram PN10 and Lipram CR10 are essentially exactly the same product, Global touts them as different substitutes for the dissimilar Pancrease and Creon products. Thus, Solvay asserts that Global is marketing different products as similar to each other, and similar products as different from each other.

II. Damages

Global categorizes the methods by which generic drugs are substituted into two distinct categories: (1) automatic substitution, whereby a pharmacist substitutes a generic for a name-brand drug without the prescribing physician's approval; and (2) proactive substitution, whereby a pharmacist seeks and receives permission from the prescribing physician before substituting the generic. Undisputedly, what Global classifies as "proactive" substitution is legal in all fifty states. Automatic substitution is governed by state law, however, and the rules by which a pharmacist may automatically substitute a generic for a name-brand drug vary from state to state. In some states, a prescription may be automatically substituted when the substitute has been approved by the FDA and

given an AB-equivalence rating, denoting that the substitute is bioequivalent to the prescribed drug. In other states, the pharmacist has discretion to determine whether the drugs are equivalent or pharmaceutically equivalent.

Global contends that Solvay's surveys sent to pharmacists and physicians are not sufficient to support Solvay's claim for damages. Specifically, Global maintains that the pharmacist surveys did not question whether Global's advertising, as opposed to reference materials, caused the pharmacists to make their automatic substitution decisions. Global further contends that Solvay's physician surveys are skewed and, nonetheless, that they establish that doctors proactively substitute Lipram-CR for Creon. Moreover, Global points to the testimony of Solvay's survey expert, who stated that the surveys provide no basis to quantify the extent of automatic substitution of Lipram for Creon. (David Stewart Dep. at 316:20-318:14 (Def's Ex. 72).)

Solvay, on the other hand, asserts that its survey results demonstrate that at least 60-65% of Lipram 10,000 and Lipram-CR sales result from automatic substitution for Creon. (*See* Brian Reisetter Report at 27-28 (Ex-S81).) Further, Solvay points to its physician surveys which demonstrate that few doctors have ever been contacted by a pharmacist for permission to substitute Lipram for Creon. (*See* David Stewart Report at 28 (Ex-S76).)

III. Solvay's Relationship with the Cystic Fibrosis Foundation

As to Global's counterclaim for tortious interference with business opportunity, Global contends that Solvay interfered with Global's relationship with the Cystic Fibrosis Foundation ("CFF"). Global asserts that in 1997 and again in 2000, Solvay personnel

met with the CFF to discuss Solvay's anti-substitution campaign. Global contends that although Global had been working independently and productively with the CFF to determine whether Lipram would be stocked and listed on the formulary of the CF Services Pharmacy (a for-profit entity run by the CFF), Solvay hijacked its efforts by falsely notifying the CFF that generic pancrelipase products were illegal and subject to regulatory action. Specifically, Global points to a draft memorandum that Solvay and/or Dr. Leslie Hendeles sent to Dr. Preston Campbell, CFF's Executive Vice President of Medical Affairs, in November 2000 titled "Illegal Generic Pancreatic Enzymes." (SOL0191852, 151978-979, Ex. 31; SOL0145280-282, Ex. 32.) Soon thereafter, Dr. Campbell wrote to Global stating that the CFF had learned of problems with pancrelipase substitution and would not add the Lipram products to the CF Services formulary. (DEF 017607-608, Ex. 35.)

In December 2000, Dr. Campbell transmitted the final version of the "Illegal Generic Pancreatic Enzymes" memorandum to the 115 United States CF care centers. (SOL 0052974-975, Ex. 36; SOL 0191836-838, Ex. 37; SOL0191839-849, Ex. 38.) Global also contends that Solvay's Vice-President of Marketing, Thomas Rowland, sent Dr. Campbell a case report form that was to be used to record adverse incidents related to pancrelipase substitution, to be gathered by the CFF and forwarded to the FDA. Although Dr. Campbell later submitted fourteen case report forms to the FDA, the FDA stated in 2004 that there was no direct evidence that substitution caused problems. (69 Fed. Reg. 23,410 (April 28, 2004) at 23411, Ex. 44.)

Basically, Global contends that prior to the filing of this lawsuit, Solvay's executives acted, to some extent, in concert with Dr. Robert Beall from the CFF to attempt to get the FDA to take certain actions against generic pancrelipase products, to no avail. Global contends that Solvay enlisted the help of Dr. Leslie Hendeles to help support its anti-substitution campaign. Soon thereafter, Dr. Hendeles sent the "illegal generics" memorandum to Solvay for content review, and then distributed the memorandum to the CFF, CF care centers, and physicians nationwide. In 2001, however, Dr. Hendeles told Solvay that the generics were not marketed illegally, but never rescinded or corrected the "illegal generics" memorandum. Global asserts that Solvay's involvement in drafting the "illegal generics" memorandum was not revealed to its recipients. In addition, Global contends that in 2003, Solvay sent form letters to physicians referring to the "illegal generics" memorandum even after Dr. Hendeles had told Solvay that he did not believe that the generics were marketed illegally. Global also points to Solvay-sponsored presentations wherein the branded products—Creon, Ultrase, Pancrease, and Pancreacarb—were referred to as the "only legal ones." In addition, Global alleges that Solvay made charitable contributions to the CFF in order to ensure that the CFF would drop Lipram from its CF Services Pharmacy formulary.

In response to these assertions, Solvay contends that the issue of generic substitution of pancrelipase supplements was a matter that long predated Solvay's relationship with the CFF. Solvay contends that the CFF was not interested in working with generic vendors, and only gave shelf space to Lipram because of Global's strategy to act as a branded company. (*See* DEF 073288-90, Ex. 51.) However, Solvay asserts

that because CF doctors were unwilling to write Lipram prescriptions without clinical data, the CFF pharmacy never received a prescription and thus returned all of the bottles that it had stocked unsold. In support of these allegations, Solvay points to Dr. Beall's testimony that his decision not to stock Lipram-CR was based on doctors' recommendations that the CFF should not carry Lipram without clinical efficacy data. (Robert Beall Dep. at Ex. 50, 103:06-22, 212:18-213:03, 291:18-292:19.) Solvay asserts that the CFF was concerned that Global's marketing of Lipram as a substitute would result in confusion and that Dr. Beall expressed these concerns to Global. (*See* Robert Beall Dep. Ex. 23 (Ex. 58).) In light of these considerations, Solvay contends that, to the extent that Global's relationship with the CFF declined, it had nothing to do with Solvay.

Moreover, Solvay contends that the "Illegal Generics" memorandum was immaterial to the CFF's decision not to stock Lipram-CR. Solvay points to Dr. Beall's testimony that the memorandum did not influence his decision and that he was not aware of Solvay's position. (Robert Beall Dep. at 214:14-18, 305:2-306:18 (Ex. 50).) In addition, Solvay asserts that it did not write the Illegal Generics memorandum or encourage Dr. Hendeles to use the language describing generics as illegal. (Thom Rowland Dep. (Ex. 59) at 42:13-43:11.) Solvay contends that it did not even receive the memo until after the CFF told the Defendants it believed that generics were illegal.

IV. Global's Laches Defense

Global contends that Solvay unreasonably delayed bringing suit to Global's prejudice. Global contends that Solvay was aware of the increasing generic competition as early as 1997, recognized Lipram was not a proper substitute in 1998, and focused on

Lipram as a competitive threat in early 1999. In addition, Global points to comparative testing that Solvay completed on Lipram in January 1999. Global also asserts that Solvay was aware of the "Profit Builders" campaign no later than 2000. Global maintains, and Solvay does not dispute, that despite knowing of Global's marketing of Lipram as an alternative or generic to Creon, Solvay never contacted Global about Global's alleged false advertising of Lipram until Solvay brought suit against Global in April 2003. Solvay, on the other hand, points to Global's 1998 marketing plan that acknowledged the potential threat of lawsuits from branded companies attempting to protect their branded products against generics. (DEF073728-44 (Ex-S108).)

Discussion

I. Standard of Review

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The court must view the evidence and the inferences that may be reasonably drawn from the evidence in the light most favorable to the nonmoving party. *Enter. Bank v. Magna Bank of Missouri*, 92 F.3d 743, 747 (8th Cir. 1996). However, as the Supreme Court has stated, "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy, and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Enter. Bank*, 92 F.3d at

747. The nonmoving party must demonstrate the existence of specific facts in the record that create a genuine issue for trial. *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986); *Krenik*, 47 F.3d at 957.

II. Defendants' Motion for Summary Judgment

Global has moved for summary judgment on four grounds. First, Global contends that Solvay inexcusably delayed filing suit to Global's prejudice, and thus the doctrine of laches should bar Solvay from recovering damages, or at least from recovering pre-filing damages. Second, Global asserts that Solvay cannot prove literal falsity of the Lipram advertisements. Third, Global asserts that because Solvay has provided little evidence that prescribing physicians were affected by Global's advertising of Lipram, Solvay cannot prove causation or recover for prescriptions of Lipram 10,000 or Lipram-CR. Finally, Global maintains that Solvay cannot quantify its damages for the substitution of Lipram for Creon because there is no evidence in the record to distinguish between legal and illegal substitution.

A. Laches

Global argues that it is entitled to summary judgment on at least some portion of Solvay's damages claim because of Solvay's nearly five-year delay in filing suit. The equitable defense of laches applies "when a claimant inexcusably delays in asserting its claim and thereby unduly prejudices the party against whom the claim ultimately is

asserted." *Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc.*, 182 F.3d 598, 602 (8th Cir. 1999). Thus, to prevail on its laches defense, Global must demonstrate by a preponderance of the evidence that (1) Solvay inexcusably delayed in asserting its claim; and (2) Global suffered undue prejudice because of that delay. (*Id*.) In determining whether the defense applies, the Court considers factors including the length of delay, the reason for the delay, the delay's effect on the defendant, and the overall fairness of permitting the plaintiff to assert its action. *Citizens and Landowners Against the Miles City/New Underwood Powerline v. Secretary, U.S. Dept. of Energy*, 683 F.2d 1171, 1174 (8th Cir. 1982).

It is undisputed that Solvay brought its Lanham Act claims against Global within the relevant statute of limitations. However, Global argues that Solvay first became aware of Lipram as a competitive threat in late 1998, when Solvay drafted its 1999 Creon Business Plan and commissioned comparative testing on Lipram 10,000. Despite knowing that Lipram was being marketed as an alternative to Creon at that time, Solvay did not notify Global that it believed Global's marketing of Lipram was improper until Solvay brought suit in 2003. Solvay, on the other hand, asserts that it pursued the action in a timely manner, and that, by any measure, Global has not established that it has been significantly prejudiced as a result of any delay in filing suit. Solvay has also moved for summary judgment to dismiss Global's defense of laches.

Global asserts that Solvay's delay is inexcusable for a variety of reasons. There is no dispute that Solvay was aware of the competitive threat of alleged generic products as early as late 1998. Global contends that despite Solvay's knowledge, and despite Solvay

having established its position in 1997 or 1998 that generic products were not true alternatives or substitutes for Creon, Solvay did not bring suit until 2003. Global asserts that if Solvay had a sufficient basis to sue Global in 2003, it had that same basis in 1998. Moreover, Global contends that in 1998, Solvay would have had knowledge of the facts and law underlying Solvay's claims and the damages that allegedly would have begun to accrue as a result of these claims. Global maintains that rather than sending a cease and desist letter, or the like, to Global early on to put them on notice that they could be sued, Solvay attempted to market against the alleged generic products like Lipram. Global asserts that it was only once Solvay realized that these marketing efforts were having little effect that Solvay decided to sue.

Solvay, on the other hand, contends that it timely pursued the action against Global. Solvay contends that its initial comparative tests of Lipram, which allegedly confirm that Lipram is not a pharmaceutical equivalent to Creon, were not completed until July 2002. In addition, Solvay asserts that it attempted to increase the awareness of substitution issues by first providing educational or marketing information to doctors, patients, and pharmacists, and that it resorted to litigation only after those efforts failed.

Global also asserts that it was prejudiced economically by Solvay's delay in filing suit. Specifically, Global contends that it spent millions of dollars on the purchase, marketing, and sale of Lipram from Lipram's introduction to the time that Solvay filed suit. Global also contends that it made strategic marketing and product development decisions that it might have made differently had it known that Solvay was going to bring suit. Moreover, Global asserts that Solvay's delay prejudiced Global by increasing the

potential liability to which they were exposed. Global contends that this potential liability threatens the company's existence, as the company will be forced into bankruptcy if Solvay is awarded the damages that it seeks.

Solvay asserts that there is no prejudice to support Global's defense of laches. Solvay points to the threat of lawsuits identified in Defendants' August 1998 Sales and Marketing plan that demonstrates that Global was not caught completely unaware of the possibility of suit. (DEF073728-44 (Ex-S108).) In addition, Solvay contends that Global's assertions that it may have changed the course of its marketing or product development are disingenuous. Solvay points to the fact that Global has not altered its position in the two-plus years since Solvay brought suit as evidence that Global would not have changed its course if it had been made aware of Solvay's threat of litigation prior to 2003.

The Court finds that neither undue delay nor significant prejudice exist here. First, without even invoking any theory of continuing violations, Solvay undisputedly brought suit within the applicable statute of limitations. Solvay spent time testing Lipram for its equivalence or substitutability to Creon, and while doing so, attempted to use the market to counteract Global's alleged false advertising before bringing suit. The Court finds nothing unreasonable or inappropriate about this approach. Moreover, even if Global could demonstrate that Solvay unreasonably delayed bringing suit, Global has not demonstrated significant prejudice. Surely, Global invested significant amounts of money in the ongoing marketing and product development of Lipram during the time that Global knew about Lipram's threat, but failed to bring suit. However, Global has not

demonstrated that its behavior would have changed significantly had it been made aware of this precise threat of suit. Moreover, Global's Sales and Marketing Plan acknowledges that Global was not caught unaware of the threat of suit. For these reasons, Global's Motion for Summary Judgment on the issue of laches is denied; Solvay's Motion for Partial Summary Judgment on Global's laches defense is granted.

B. Lanham Act

Global has also moved for summary judgment, asserting that there are no literally false statements in their commercial advertising for Lipram. To establish a Lanham Act claim, a plaintiff must demonstrate that: (1) the defendant made a false statement of fact in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material; (4) the defendant caused its false statement to enter into interstate commerce; and (5) plaintiff has been or is likely to be injured as a result of the false statement. *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998). In addition, to recover money damages under the Lanham Act, a plaintiff must prove both actual damages and a causal link between a defendant's actions and those damages. *Id*.

The false statement necessary to establish a Lanham Act violation generally falls into one of two categories: (1) commercial claims that are literally false as a factual matter; and (2) claims that may be literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or are likely to deceive consumers. *Id*. (citing *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)). In determining whether an advertisement is literally false, the court analyzes the

message conveyed within its full context. *Id*. A statement is deemed literally false if it conveys a "specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact." *Heidi Ott A.G. v. Target Corp.*, 153 F. Supp. 2d 1055, 1069 (D. Minn. 2001). Literally false statements are distinguished from puffery, which the Eighth Circuit has defined as "exaggerated advertising, blustering, and boasting upon which no reasonable buyer would rely and is not actionable" under the Lanham Act. *Id*., quoting *Southland Sod Farms*, 108 F.3d at 1145. Such non-actionable puffery includes "representations of product superiority that are vague or highly subjective." *Id*.

Global contends that Solvay cannot establish literal falsity as to several statements. First, Global contends that there is no literal falsity as to Global's statements that Lipram was stocked by the CF Services Pharmacy and that Lipram is a high-quality product. Second, Global contends that the statements that Lipram is as safe and effective as Creon, "substitutable" for Creon, and meeting USP standards are literally true. Third, Global asserts that the statements that Lipram is an "alternative" or "comparable" to Creon are literally true, or at most, non-actionable puffery. Finally, Global contends that the statements that Lipram is "equivalent" to or a "generic" for Creon convey more than one possible message, and are thus not literally false under the Lanham Act.

The Court finds that genuine issues of material fact exist as to the literal falsity of most of these statements.[1] Global's own witnesses admit that pharmacists understand the terms "pharmaceutical alternative," "alternative," and "generic alternative" to be synonymous and to mean that Lipram is equivalent to Creon. Global advertises Lipram to have the identical active ingredients in the exact amounts of Creon, yet Solvay sets forth evidence that Lipram contains different active ingredients and strengths. Global designates Lipram with a suffix for each name-brand product for which Lipram is allegedly a substitute or alternative, and advertises that its version of Lipram matches the name-brand product that the Lipram suffix identifies. For instance, Lipram CR10 is marketed as equivalent to Creon 10. However, it is undisputed that although Global is marketing Lipram as an "alternative" to these name-brand supplements (namely, Creon, Pancrease, and Ultrase), and the labeling specifies that these supplements are specially formulated to match each name-brand drug, the supplements all contain exactly the same active ingredients, but each wears a different name and label. Considering that fact questions exist as to whether Lipram even contains the same ingredients as Creon, the Court finds that genuine issues of fact exist as to whether Lipram could be as safe and effective as Creon or an alternative, substitute, equivalent, generic alternative, or comparable to Creon. Solvay also has raised sufficient evidence to create a genuine issue

[1] Because Solvay does not contest Global's arguments that Lipram is truly stocked in the CF Services Pharmacy, the Court does not address this statement. Moreover, the Court finds that Global's statement that Lipram is a "high quality" product is subjective puffery and not actionable under the Lanham Act. Global's Motion for Summary Judgment is granted as to these two statements.

of fact as to whether there may be therapeutic failures associated with Lipram that render Lipram an unsafe automatic substitute for Creon. Finally, the parties' testing differs as to whether Lipram-CR may have exceeded USP limits and thus may not meet USP requirements.

Global further asserts that there is insufficient evidence to award Solvay damages for Lipram prescriptions and that there is no basis in the record to properly quantify any damages that Solvay allegedly suffered. Proof of literally false advertising entitles a plaintiff to a presumption of actual consumer deception and the fact of harm. *Porous Media Corp. v. Pall Corp.*, 110 F.3d 1329, 1333 (8th Cir. 1997); *see also 3M Innovative Props. Co. v. DuPont Dow Elastomers LLC*, 361 F. Supp. 2d 958, 971 (D. Minn. 2005). However, the plaintiff must still prove an evidentiary basis for any actual harm caused. *Porous Media Corp*., 110 F.3d at 1333.

Global contends that there is no evidence in the record that Global's advertising influenced any doctor who prescribed Lipram. Thus, Global asserts that, to the extent that Solvay has asserted damages based on prescriptions written for Lipram, the claims of damages should be dismissed. Global further asserts that Solvay has no means to quantify its damages claims against Global. Specifically, Global contends that it is impossible to distinguish between the so-called "lawful" or "legal" substitutions of Lipram for Creon and those sales or substitutions that were allegedly caused by false or misleading advertising. Solvay, on the other hand, asserts that the Lipram prescriptions are not what they seem. Solvay posits that these Lipram prescriptions may have begun as prescriptions for Creon, but were later re-coded as new prescriptions for Lipram,

consistent with pharmacy practice, after the pharmacist contacted the prescribing physician for authorization to substitute Lipram. Solvay argues that this is a logical explanation for the thousands of Lipram prescriptions from doctors who, according to Solvay's surveys, had never heard of Lipram. Moreover, Solvay contends that its measure of damages is not purely speculative. Solvay asserts that once Global, through its allegedly false or misleading advertising, convinced pharmacists that Lipram was an appropriate generic substitute for Creon, Global relied on pharmacists to pass this very same information along to physicians as they sought to gain substitutions.

Drawing all permissible inferences in favor of Solvay, the Court finds that summary judgment is inappropriate on these issues. Global's marketing moved to arm pharmacists with the knowledge sufficient to encourage generic usage. Based on Global's marketing plan, a jury could draw an inference that Global's marketing was done with the expectation that pharmacists would encourage physicians to substitute Lipram for Creon, and thus with the expectation that pharmacists would pass the allegedly false advertising message on to physicians, with the "snowball effect" that Solvay alleges. Global's former CEO's testimony that the marketing plan encouraged the pharmacist to "sell the product" by detailing a physician on the allegedly alternative supplements supports this theory. (Max Mendelsohn Dep. at 62:21-63:08 (Ex-S33).) Thus, although Global's advertisements for Lipram may have been once-removed from the hands of physicians themselves, the allegedly false or misleading advertisements would have had the same effect as if the prescribing physicians had read them. Solvay has raised a logical chain of causation to support an inference of damages based on

Lipram prescriptions. In addition, the Court finds that Solvay has set forth sufficient evidence by which a jury could quantify Solvay's damages. For these reasons, Global's Motion for Summary Judgment is denied on this issue.

C. Remaining Issues

Solvay has moved for summary judgment to dismiss Global's counter-claim of tortious interference with business opportunity. The Court finds that Global has raised evidence to support that genuine issues of material fact exist as to whether Solvay and its agents played a role in convincing the CFF to discontinue business with Global. Based on the conflicting evidence before the Court, a jury could find that Lipram is indeed an appropriate generic or alternative substitute to Creon, and that Solvay acted to harm Global's existing or potential business relationship with the CFF. As a result, Solvay's motion for summary judgment is denied on this issue and on the issue of Global's defense of unclean hands.

Finally, Solvay has moved for summary judgment on Global's affirmative defenses related, basically, to whether Solvay has attempted to usurp the United States Food and Drug Administration's rules. The Court does not intend to relitigate issues that were already disposed of in the Court's Order denying, in part, Global's Motion to Dismiss. (*See Solvay Pharmaceuticals, Inc. v. Global Pharmaceuticals*, 298 F. Supp. 2d 880, 884–85 (D. Minn. 2004). Thus, to the extent that Global is attempting to reassert that Solvay's claims fall within the jurisdiction of the FDA, or that the claims attempt to circumvent the authority of the FDA, Solvay's motion for summary judgment on these defenses is granted.

For the reasons stated, **IT IS HEREBY ORDERED THAT**:

1. Defendants' Motion for Summary Judgment (Doc. No. 122) is **GRANTED IN PART and DENIED IN PART**, as follows:

   a. Defendants' Motion on the issue of laches is **DENIED**;

   b. Defendants' Motion on the issue of damages is **DENIED**;

   c. Defendants' Motion on the issue of literal falsity is **GRANTED IN PART** and **DENIED IN PART**.

2. Plaintiff's Motion for Partial Summary Judgment (Doc. No. 116) is **GRANTED IN PART and DENIED IN PART**, as follows:

   a. Plaintiff's Motion on the issue of laches is **GRANTED**;

   b. Plaintiff's Motion on the issue of Defendants' Counterclaim and defense of unclean hands is **DENIED**;

   c. Plaintiff's Motion on the issue of Defendants' FDA affirmative defenses is **GRANTED**.

Dated: March 14, 2006

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court